

Atty Dkt No. CARL3003/REF
USSN: 09/868,243
PATENT

1.0 mg of CTB, and the [physiologically acceptable] buffer solution is phosphate buffered saline solution.

REMARKS

Introductory Comments:

Claims 1-4 are pending and were examined in the Office Action dated 5 June 2002. Applicants note with appreciation that the Office has acknowledged applicants' claims to priority and the Information Disclosure Statement filed 15 June 2001. However, the following claim objections/rejections have been entered: (a) claims 1-4 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite; and (b) claims 1 and 4 were objected to on the basis of clarity.

All standing rejections and objections are respectfully traversed for the reasons discussed herein below.

Overview of the Amendments:

Applicants, by way of this Amendment, have provided a number of minor amendments to claims 1-4. More particularly, all of the listed claims have been amended to replace "Oral vaccine" with "An oral vaccine" in the preamble of each claim. In addition, a number of phrases objected to by the Office have been removed, mostly as helpfully suggested by the Office, a clarifying amendments have been made where appropriate. Support for the amendments can thus be found throughout the specification and in the claims as originally filed. Accordingly, no new matter has been added by way of these claim amendments, and the entry thereof is respectfully requested.

A marked-up version of the changes made to the claims by the current Amendment is attached and appears herein above. The attached page is captioned "Version With Markings to Show Changes Made."

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The Rejection under 35 U.S.C. §112, second paragraph:

Claims 1-4 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. Initially, the Office has objected that use of the recitation "an vehicle" in claim 1 is unclear. The Office had suggested replacing the recitation with --a physiologically acceptable vehicle-- and then deleting recitation of "physiologically acceptable" from claims 2 and 3 to obviate the rejection.

In response, applicants draw the Office's attention to the amendments to the claims wherein these changes have been made.

Claim 1 further stood rejected on the basis that the recitation of "defined amount" is a relative term and unclear. Clarification or correction was requested.

In response, applicants draw the Office's attention to the amendments to claims 1-4 wherein the phrase "defined amount" has been removed and the claim language clarified as requested by the Office.

Claim 1 was further objected to on the basis that recitation of "vaccine composition is purified from possible heat stable enterotoxin" is confusing. Clarification or correction was requested.

In response, applicants draw the Office's attention to the amendment to claim 1, wherein the offending language has been removed, and the claim now more clearly recites that the vaccine composition does not contain the subject toxin.

Finally, claims 2-4 were rejected on the basis that the base claim (claim 1) was indefinite.

Applicants submit that the amendments to the claims tendered herewith are sufficient to overcome all of the rejections under 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the rejections is thus respectfully requested.

The Objections to the claims:

Claims 1 and 4 were objected to on the following grounds: applicants were requested to insert "an" in the preamble of each claim; clarification of the recitation of

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"enterotoxigenic *E. coli* caused diarrhea" was requested; the Office requested that recitation of "possible" be removed; and the Office requested that the grammatical errors "amount are" and "an vehicle" be corrected.

In response, applicants draw the Office's attention to the amendments to claims 1 and 4, wherein all of the Office's requested changes have been made, obviating the claim objections. Reconsideration and withdrawal of the objections to claims 1 and 4 is thus respectfully requested.

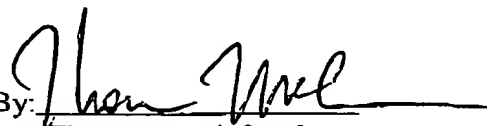
CONCLUSION

Applicants respectfully submit that the claims as now pending define an invention which complies with the requirements of 35 U.S.C. § 112 and which is novel and nonobvious over the art. Accordingly, allowance is believed to be in order and an early notification to that effect is earnestly solicited. Applicants further ask that, should the Examiner note any minor remaining issues that may be resolved with a telephone call, that the Examiner contact the undersigned in the UK at +44 1865 332 600.

Respectfully submitted,

Date: 5 December 2002

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